

NOT FOR PUBLICATION

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

JAZZ PHARMACEUTICALS, INC.,

Plaintiff,

v.

ROXANE LABORATORIES, INC.

Defendant.

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Civil Action No. 10-6108 (ES)(MAH)

OPINION & ORDER

SALAS, DISTRICT JUDGE

Plaintiff Jazz Pharmaceuticals, Inc. (“Jazz”) partially appeals an Order by Magistrate Judge Michael A. Hammer, (D.E. No. 366), permitting Defendant Roxane Laboratories, Inc. (“Roxane”) to serve amended invalidity and non-infringement contentions. (D.E. No. 372). For the reasons below, Jazz’s partial appeal is denied.

I. BACKGROUND

This motion arises from Judge Hammer’s decision to permit Roxane to amend its invalidity and non-infringement contentions pertaining to claims 1 and 6 of U.S. Patent No. 6,472,431 (the “431 patent”). (D.E. No. 366).

On April 14, 2011, Roxane served its invalidity contentions on Jazz pursuant to Local Patent Rule 3.3. (See D.E. No. 373, Jazz Pharmaceuticals, Inc.’s Brief in Support of its Partial Appeal of Magistrate Judge Hammer’s October 3, 2014 Order (“Pl. Mov. Br.”) at 1). In its invalidity contentions, Roxane did not contend that the claim element “pH-adjusting agent” was present in the prior art based on the disclosure of gamma butyrolactone (“GBL”), an organic acid found in Roxane’s ANDA product. (*Id.*).

On August 24, 2011, Jazz served its infringement contentions on Roxane pursuant to Local Patent Rule 3.1. (*Id.*). In its infringement contentions, Jazz asserted that the claim element “pH-adjusting agent” was met by Roxane’s use of GBL in its process. (*Id.*).

On December 5, 2011, the parties served their opening *Markman* briefs, setting forth their claim construction positions regarding the ‘431 patent. (D.E. No. 77, Roxane Laboratories, Inc.’s Opening *Markman* Brief (“Roxane *Markman* Br.”) at 3-11; D.E. No. 80, Jazz Pharmaceuticals, Inc.’s Opening *Markman* Brief (“Jazz *Markman* Br.”) at 5-18).

Roxane proposed that the Court construe the term “pH-adjusting agent” in claims 1 and 6 of the ‘431 patent to mean “[a]n agent, which is an acid or base, directly added primarily to alter the pH.” (Roxane *Markman* Br. at 8). Jazz took the position that there was “no construction necessary” for the claim element “pH-adjusting agent” because the plain and ordinary meaning is consistent with the statement in the patent’s specification that pH-adjusting agents are used “to create compositions that achieve a desired pH.” (Jazz *Markman* Br. at 17 (quoting ‘431 patent at 7:19-24)).

In its September 14, 2012 *Markman* ruling, the Court construed “pH-adjusting agent” to mean “[c]ompositions that achieve a desired pH.” (D.E. No. 151, *Markman* Opinion (“*Markman* Op.”) at 19-21). This construction was not proposed by either party.

On November 5, 2012, Roxane submitted a letter motion seeking to amend its invalidity contentions regarding the ‘431 patent, as well as its invalidity and noninfringement contentions for claims pertaining to other patents-in-suit. (D.E. No. 177, Letter Motion). With respect to the ‘431 patent, Roxane sought to amend its contentions to assert a certain prior art reference, Chem Abstract ES 302388 (“CA 338”), against the “pH-adjusting agent” limitation in claims 1 and 6.

(*Id.* at 5-6). Jazz opposed the proposed amendments. (D.E. No. 184, Letter Opposition).

On October 3, 2014, Judge Hammer read into the record a ruling granting the totality of Roxane's request to amend its contentions. (D.E. No. 368, Oct. 3, 2014 Transcript ("Tr."); *see also* D.E. No. 366, Order).

On October 20, 2014, Jazz appealed the portion of Judge Hammer's ruling relating to the claim term "pH-adjusting agent." (Pl. Mov. Br. at 3 n.3). Roxane opposed the appeal on November 3, 2014. (D.E. No. 379, Opposition of Roxane Laboratories, Inc. to Jazz's Partial Appeal of Magistrate Judge's October 3, 2014 Ruling ("Def. Opp. Br.")). Jazz replied on November 10, 2014. (D.E. No. 383, Jazz's Reply Memorandum of Law in Further Support of its Appeal of Magistrate Judge Hammer's October 3, 2014 Order ("Pl. Rep. Br.")).

In addition, Jazz submitted a supplemental letter regarding its partial appeal on March 4, 2015. (D.E. No. 402). Roxane responded on March 5, 2015. (D.E. No. 403).

II. STANDARD OF REVIEW

"Any party may appeal from a Magistrate Judge's determination of a non-dispositive matter within 14 days after that party has been served a copy of the Magistrate Judge's order" L. Civ. R. 72.1(c)(1)(A). A district court may reverse a magistrate judge's determination of a non-dispositive issue only if it is "clearly erroneous or contrary to law." *Id.*; *see also* 28 U.S.C. § 636(b)(1)(A); Fed. R. Civ. P. 72(a); *Cipollone v. Liggett Grp., Inc.*, 785 F.2d 1108, 1113 (3d Cir. 1986).

A magistrate judge's decision is clearly erroneous "when although there is evidence to support it, the reviewing court on the entire evidence is left with the definite and firm conviction that a mistake has been committed." *United States v. U.S. Gypsum Co.*, 333 U.S. 364, 395 (1948).

A magistrate's judge decision is "contrary to law" when the magistrate judge "misinterpreted or misapplied the applicable law." *Doe v. Hartford Life and Accident Ins. Co.*, 237 F.R.D. 545, 548 (D.N.J. 2006).

III. DISCUSSION

A. Standard for Amendments to Contentions

Local Patent Rule 3.7 provides that "[a]mendment of any contentions, disclosures, or other documents required to be filed or exchanged pursuant to these Local Patent Rules may be made only by order of the Court upon a timely application and showing of good cause." L. Pat. R. 3.7. It further states that "[n]on-exhaustive examples of circumstances that may, absent undue prejudice to the adverse party, support a finding of good cause include: (a) a claim construction by the Court different from that proposed by the party seeking amendment." *Id.* The moving party has the burden of demonstrating good cause. *02 Micro Int'l Ltd. v. Monolithic Power Sys., Inc.*, 467 F.3d 1355, 1366 (Fed. Cir. 2006).

Though a different claim construction by the Court *may* support a finding of good cause, courts in this district have made clear that "a *Markman* ruling is not a 'free pass' to grant motions to amend contentions. The moving party still has to show that it acted diligently to determine that the amendment was necessary." *Horizon Pharma AG v. Watson Labs., Inc. – FL*, No. 13-5124, D.E. No. 138 at 14 (D.N.J. Feb. 24, 2015). Indeed, diligence is a "key factor" in determining whether good cause exists to amend. *Id.* at 5; *see also Prometheus Labs. Inc. v. Roxane Labs., Inc.*, No. 11-1241, D.E. No. 174 at 13-14 (D.N.J. Aug. 6, 2012).

B. Judge Hammer's Decision was Not Clearly Erroneous or Contrary to Law

Jazz argues that "Judge Hammer erred as a matter of law by failing to consider the diligence

requirement and beginning and ending his inquiry into good cause based on the mere existence of a ‘different construction.’” (Pl. Mov. Br. at 5). The Court disagrees. Judge Hammer considered the diligence requirement, and soundly reached the conclusion that Roxane was diligent in seeking to amend its contentions. (Tr. at 18-20).

To start, in summarizing the appropriate legal standard, Judge Hammer explained that “[g]ood cause ‘considers first whether the moving party was diligent in amending its contentions, and then whether the nonmoving party would suffer prejudice if the motion to amend were granted.’” (Tr. at 7 (quoting *AstraZeneca AB v. Dr. Reddy’s Labs Inc.*, No. 11-2317, 2013 U.S. Dist. LEXIS 36779, at *8 (D.N.J. Mar. 18, 2013))). Judge Hammer expressly recognized the importance of assessing diligence, further explaining that “[c]learly, good cause ‘requires a showing of diligence.’” (*Id.* (quoting *02 Micro*, 367 F.3d at 1366)).

Judge Hammer then proceeded to evaluate Jazz’s argument that “the amendments proposed by Roxane concerning the ‘431 Patent are untimely” because Roxane was aware of Jazz’s arguments since it served its infringement contentions on Roxane in August 2011. (*Id.* at 19). Judge Hammer disagreed with Jazz’s argument, noting its inconsistency with Local Patent Rule 3.7, which expressly recognizes that good cause may exist for a party to amend contentions after claim construction by the Court—so long as the amending party is diligent and undue prejudice does not result. (*Id.*). Judge Hammer then distinguished this case from others where the party seeking amendment did not act diligently, including *Prometheus*, which Jazz relied on. Specifically, Judge Hammer found that the present case is distinguishable from *Prometheus* because, here, “[t]he only prior art reference in the proposed amended contentions . . . was already disclosed in the initial contentions.” (Tr. at 20). Judge Hammer further noted that Roxane moved

to amend its contentions “within weeks of the court’s claim construction opinion.” (*Id.*). Thus, Judge Hammer clearly considered the diligence requirement in reaching his decision.

Not only did Judge Hammer properly consider whether Roxane was diligent in seeking amendment, but the Court finds no clear error in the conclusion reached. First, as Judge Hammer discussed, Roxane was diligent in seeking amendment within weeks of the Court’s claim construction Opinion. (Tr. at 20). Jazz argues that Roxane lacked diligence because it became aware of Jazz’s position that the claim element “pH-adjusting agent” was met by Roxane’s use of GBL in its process when Jazz filed its infringement contentions in August 2011. (Pl. Mov. Br. at 4-6). But this argument ignores the fact that Jazz’s proposed claim construction of the term “pH-adjusting agent” was “no construction necessary.” (*Jazz Markman* Br. at 17). Regardless of its knowledge of Jazz’s position, Roxane could have argued that GBL does not meet the element “pH-adjusting agent” under either its proposed construction or Jazz’s proposed “no construction necessary.” Roxane therefore could have believed that it did not need to amend its contentions as long as the Court agreed with either party’s position. However, the Court issued a construction that was not proposed by either party. (*Markman* Op. at 19-21). As Roxane points out in its brief, “Jazz has cited to no case law requiring a defendant to anticipate a court’s own construction that is different than that proposed by either party.” (Def. Opp. Br. at 8). In *Prometheus*, for example, the defendant “had a duty to formulate any invalidity defenses *directed at plaintiff’s proposed constructions* as soon as it received them and promptly seek to amend contentions.” *Prometheus*, D.E. No. 174 at 16 (emphasis added). Similarly, in *Horizon Pharma AG v. Watson Labs., Inc. – Florida*, No. 13-5124, D.E. No. 138 at 13 (D.N.J. Feb. 24, 2015), the court determined that “defendant was on notice of *plaintiffs’* claim construction . . . that the Court eventually adopted.”

(emphasis added). The court in *Horizon* even noted that “perhaps . . . if the *Markman* ruling was unexpected defendant would have a better argument.” *Id.* The Court therefore agrees with Judge Hammer that Roxane has demonstrated diligence by seeking to amend its contentions within weeks of the Court’s claim construction Opinion.

In addition, the Court does not find that Jazz will be significantly prejudiced by Roxane’s amendment. Jazz argues that, by amending its contentions, Roxane seeks to add a new defense and prior art reference with respect to the claim element “pH-adjusting agent.” (Pl. Rep. Br. at 4). It further argues that it is “immaterial” that Roxane is already asserting the reference, CA 338, against claim elements in other patents-in-suit. (*Id.* at 6). The Court disagrees. The fact that CA 338 is already part of this case and has been asserted against similar claim elements in a different patent alleviates the prejudice that Jazz faces if the reference is also asserted against the ‘431 patent. In addition, as Judge Hammer noted in his decision, Roxane only seeks to add one reference. This further distinguishes this case from others, including *Prometheus*, where amended contentions adding multiple references were prohibited. (*See* Def. Opp. Br. at 8 (collecting cases)).

IV. CONCLUSION

For the foregoing reasons, the Court finds that Judge Hammer’s ruling was not clearly erroneous or contrary to law, and Jazz’s partial appeal of Judge Hammer’s decision is denied.

Accordingly, it is on this 19th day of June 2015,

ORDERED that Plaintiff Jazz Pharmaceuticals, Inc.’s partial appeal of Magistrate Judge Michael A. Hammer Order, (D.E. No. 366), is denied; and it is further

ORDERED that the Clerk of the Court may terminate the motion, (D.E. No. 372).

SO ORDERED.

s/ Esther Salas
Esther Salas, U.S.D.J.